## REMARKS

According to the Notice of Non-Compliant Amendment dated October 29, 2009, the listing of claims in Applicant's submission dated June 30, 2009, included incorrect claim identifiers. Please disregard the submission dated June 30, 2009, and instead enter claims 11, 21, 22 and 24-39 as set forth in the claim listing provided herewith. Claims 11, 21, 22 and 24-39 are pending and under examination in the above-identified application. Claims 11, 22, 34 and 39 have been amended above. Entry of the amendments, which add no new matter, is respectfully requested.

### Regarding 35 U.S.C. § 112, First Paragraph (Written Description)

Applicants respectfully traverse the rejection of claim 34 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, had possession of the claimed invention at the time the application was filed.

The Office alleges that Applicants have not described the genus of polynucleotides reading on a single nucleotide sequence comprising SEQ ID NO: 1175 that are also diagnostic of colon, breast or prostate cancers. (Office Action, page 3). Because one of skill in the art would readily appreciate that the inventors had possession of the claimed invention at the time the present application was filed, Applicants respectfully traverse.

The Examiner's reliance on *Regents v. Eli Lilly* is misplaced. In that case, the patent specification at issue did not identify the sequence (structure) of any embodiment of DNA claimed therein. *See Eli Lilly*, 119 F.3d at 1567-68 (affirming a judgment that the claim requiring cDNA encoding human insulin was invalid for failing to provide an adequate written description where the specification described the human insulin A and B chain amino acid sequences encoded by the cDNA, but did not provide the nucleotide sequence for the cDNA itself).

*Enzo Biochem v. Gen-Probe, Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) ("Enzo Biochem II"), stated that "the written description requirement would be met for all of the claims [of the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or

disclosed." In *Invitrogen v. Clontech*, the Federal Circuit held that the disclosure of a single genetically-engineered functional variant of a known protein was sufficient to provideadequate written description to support a claim encompassing essentially any engineered variant of the protein sharing the modified function. 429 F.3d 1052 (Fed. Cir 2005)

The specification provides sufficient written description for the pending claims as evidenced by the U.S. Patent and Trademark Office's own guidelines on the subject: Synopsis of Application of Written Description Guidelines, www.uspto.gov/web/menu/written.pdf ("Guidelines"). Example 14 of the Guidelines illustrates a hypothetical situation that mirrors the present case. Example 14 provides an example of a product by function claim, where the specification teaches that SEQ ID NO:3 and "variants that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A→B" are essential to the operation of the claimed invention.

Example 14 then provides the following guidance to examiners:

> The specification indicates that the genus of [nucleic acids] that must be variants of SEQ ID NO:3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO:3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified [kinase-encoding] activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus.
> Conclusion: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.

As in the Example 14 hypothetical, the present claims are drawn to a genus of molecules whose "variants must possess the specified activity and must have identity to" a reference sequence. The polynucleotide of claim 34 must have at least 98% sequence identity to SEQ ID NO:1175. The level of recited sequence identity in claim 34 is at least 98%, significantly higher than the level of identity recited in Example 14 of the Guidelines, thereby further increasing the required similarity between members of the genus. The present application discloses the species SEQ ID

NO:1175 and information relating to variants. Applicants respectfully request removal of the rejection of claim 34 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, had possession of the claimed invention at the time the application was filed.

**Rejections Under 35 U.S.C. § 102**

Applicants respectfully traverse the rejection of claims 11, 21, 22 and 24-38 under 35 U.S.C. § 102(b) as allegedly being anticipated by Sikut et al., *Biochemical and Biophysical Research Communications* 238:612-616 (1997). Although Applicants do not agree that the cited reference anticipates the rejected claims, in an attempt to further prosecution of the pending claims to allowance, claims 11, 22, 34, and 39 have been amended, rendering the rejection moot.

Applicants respectfully traverse the rejection of claims 22, 24-29 and 31-38 under 35 U.S.C. § 102(b) as allegedly being anticipated by Sikut et al., *Int'l J. Cancer* 82(1):52-58 (1999). Although Applicants do not agree that the cited reference anticipates the rejected claims, in an attempt to further prosecution of the pending claims to allowance, claims 11, 22, 34, and 39 have been amended, rendering the rejection moot.

Applicants respectfully traverse the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by Topalovski et al., *Arch. Pathol. Lab Med.* 123:1208-1218 (1999). Topalovski et al., discloses CD43 merely marker that is used, along with a host of other markers, to immunophenotype the cell type of breast lymphomas as B-cell versus T-cell. Like Aguilera et al. discussed below, Topalovski et al. do not teach all elements of the claimed invention. However, anticipation requires that "each element of the claim at issue is found, either expressly described or under the principles of inherency, in a single prior art reference or that the claimed invention was previously known or embodied in a single prior art device or practice." Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983). See *MEHL/Biophile Int'l Corp. v Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (to anticipate, a single reference must teach every limitation of the claimed invention; any limitation not explicitly taught must be inherently taught and would be so understood by a person experienced in the field); *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991) (the dispositive

question is "whether one skilled in the art would reasonably understand or infer" that a reference teaches or discloses all of the elements of the claimed invention); *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) (to anticipate, every element of the claims must appear in a single prior art reference, or if not expressly shown, then demonstrated to be known to persons experienced in the field of technology); *In re Samour*, 571 F.2d 559, 562 (CCPA 1978) (the key question is whether a single prior art reference "publicly discloses every material element of the claimed subject matter"). Because Topalovski et al. do not teach all elements of the claimed invention, Applicants respectfully request removal of the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by Topalovski et al., *Arch. Pathol. Lab Med.* 123:1208-1218 (1999).

Applicants respectfully traverse the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by Aguilera et al., *Mod. Pathol.* 13(6):599-604 (1999).

Aguilera et al., discloses CD43 merely as a T-cell marker. Aguilera et al. appears to be directed to a rare form of breast lymphoma, which is T cell derived rather than the more common B-cell breast lymphoma. CD43 is mentioned only as one of three markers that were used solely to identify the cell type of the cancer tissue as T-cell. As conceded by the Examiner at pages 9/10 of the Office Action, "Aguilera et al. does not teach the comparison of a tumorous patient sample with a normal sample, nor the hybridization of a polynucleotide that hybridizes under the designated hybridization conditions set forth in claim 39 with SEQ ID NO;1175." This, the Examiner correctly point out that Aguilera et al. do not teach all elements of the claimed invention. However, anticipation requires that "each element of the claim at issue is found, either expressly described or under the principles of inherency, in a single prior art reference or that the claimed invention was previously known or embodied in a single prior art device or practice." Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983). See *MEHL/Biophile Int'l Corp. v Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (to anticipate, a single reference must teach every limitation of the claimed invention; any limitation not explicitly taught must be inherently taught and would be so understood by a person experienced in the field); *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991) (the dispositive question is "whether one skilled in the art would reasonably understand or infer" that a reference

teaches or discloses all of the elements of the claimed invention); *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) (to anticipate, every element of the claims must appear in a single prior art reference, or if not expressly shown, then demonstrated to be known to persons experienced in the field of technology); *In re Samour*, 571 F.2d 559, 562 (CCPA 1978) (the key question is whether a single prior art reference "publicly discloses every material element of the claimed subject matter"). Because Aguilera et al. do not teach all elements of the claimed invention, Applicants respectfully request removal of the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 102(b) as allegedly being anticipated by Aguilera et al., *Mod. Pathol.* 13(6):599-604 (1999).

Lastly, it is noted that the Office Action fails to specifically address even the expressly recited features of several of the pending dependent claims. Under the Office's policy of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. (MPEP §707.07(g)). Accordingly, in the event that the Office maintains the rejection of any of the dependent claims, Applicants respectfully request, in the interests of compact prosecution, that the Office apply art against each feature of each rejected dependent claim, on the record, and with specificity sufficient to support a *prima facie* case of anticipation.

**Regarding 35 U.S.C. § 103**

Applicants respectfully traverse the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sikut et al., *Biochemical and Biophysical Research Communications* 238:612-616 (1997) and in further view of U.S. Patent Publication 2004/0038207. Although Applicants do not agree that the cited reference anticipates the rejected claims, in an attempt to further prosecution of the pending claims to allowance, claims 11, 22, 34, and 39 have been amended, rendering the rejection moot.

Applicants respectfully traverse the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sikut et al., *Int'l J. Cancer* 82(1):52-58 (1999) and in further view of U.S. Patent Publication 2004/0038207. Although Applicants do not agree that the cited reference anticipates the rejected claims, in an attempt to further

prosecution of the pending claims to allowance, claims 11, 22, 34, and 39 have been amended, rendering the rejection moot.

Applicants respectfully traverse the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Aguilera et al., *Mod. Pathol.* 13(6):599-604 (1999) and in further view of U.S. Patent Publication 2004/0038207.

The examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3 1531, 1532, (Fed. Cir. 1993). Aguilera et al. does not disclose "a method of detecting CD43 breast cancers utilizing immunohistochemistry" as suggested by the Examiner at page 7 of the Office Action. Aguilera et al., discloses CD43 merely as a T-cell marker. Aguilera et al. appears to be directed to a rare form of breast lymphoma, which is T cell derived rather than the more common B-cell breast lymphoma. CD43 is mentioned only as one of three markers that were used solely to identify the cell type of the cancer tissue as T-cell. Accordingly there would be no motivation by the skilled person to combine Aguilera et al. with the cited secondary references. Accordingly, based on the deficiencies of the primary reference as described above and the fact that the cited secondary reference does not cure the deficiencies of Aguilera et al., removal of the rejection of claims 11, 21, 22 and 24-39 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Aguilera et al., *Mod. Pathol.* 13(6):599-604 (1999) and in further view of U.S. Patent Publication 2004/0038207, is respectfully requested.

Lastly, it is noted that the Office Action fails to specifically address even the expressly recited features of several of the pending dependent claims. Under the Office's policy of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. (MPEP §707.07(g)). Accordingly, in the event that the Office maintains the rejection of any of the dependent claims, Applicants respectfully request, in the interests of compact prosecution, that the Office apply art against each feature of each rejected dependent claim, on the record, and with specificity sufficient to support a *prima facie* case of obviousness.

## CONCLUSION

In light of the Amendments and Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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